



# Old Drugs, New Uses: Solving a Hatch-Waxman Patent Predicament

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# Old Drugs, New Uses

Solving a Hatch-Waxman Patent Predicament

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## Abstract

In early 2003, two panels of the Federal Circuit clashed in a pair of cases (*Warner-Lambert v. Apotex* and *Allergan v. Alcon*) dealing with the question of whether an action for inducement of infringement could be leveled against a generic drug manufacturer seeking FDA approval for an unpatented drug with both patented and unpatented uses. This paper takes up this debate, analyzing the interpretive puzzles presented in the application of the intricate Hatch-Waxman Act to this set of facts, arguing that the correct interpretation weaves elements from both panels' approaches. It finishes with an alternative solution borrowed from a lesson in copyright.

If the Second Amendment had a penumbra, it might look something like, "The People have a right to objects that can potentially be put to bad purposes."<sup>1</sup> The problem is figuring out what the scope of that right ought to be — how to maximize the benefits of use and minimize the harms of abuse. The question is as old as guns,<sup>2</sup> as new as digital video,<sup>3</sup> and sometimes as silly as martini-olive transmitters<sup>4</sup> and aluminum-lined backpacks.<sup>5</sup> Of course, it applies to drugs. And more and more, it is confounding consumers and corporations alike in the context of intellectual property.

Consider, for example, a pair of high-profile copyright cases from the last twenty years in which the question was squarely faced in decisions that ultimately came down in opposing directions. First, in *Sony v. Universal*, a bare majority of the Supreme Court held that Sony Corporation could not be held contributorily liable for the sale of the VCR, since the device was "capable of... substantial noninfringing use."<sup>6</sup> In other words, the Supreme Court was willing to curtail some rights of copyright holders so as to protect "fair uses rights" for those who would utilize VCRs for legitimate purposes. In *A&M Records v. Napster*, however, a panel of

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<sup>1</sup>See U.S. CONST. amend. II ("A well regulated militia, being necessary to the security of a free state, the right of the people to keep and bear arms, shall not be infringed."); *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965).

<sup>2</sup>*Id.*

<sup>3</sup>*Universal City Studios, Inc. v. Corley*, 273 F.3d 429 (2nd Cir. 2001) (enjoining an online site from distributing software capable of cracking access protection technologies embedded in DVDs in order to make copies of movies).

<sup>4</sup>See S. REP. NO. 90-351 (1968), reprinted in 1968 U.S.C.C.A.N. 2112, 2183 (describing provisions of Title III of the Omnibus Crime Control and Safe Streets Act of 1968 banning trade in wiretapping and eavesdropping devices, including "the microphone disguised as a wristwatch, picture frame, cuff link, tie clip, fountain pen, stapler, or cigarette pack").

<sup>5</sup>MISS. CODE § 97-23-93.1; R.I. CODE § 11-63-1; COL. CODE § 18-4-417; N.H. CODE § 637:10-a (regulating "theft detection shielding devices" and "theft detection device removers" that may be used to facilitate theft of electronically-tagged goods from stores).

<sup>6</sup>*Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417 (1984).

the Ninth Circuit upheld an order mandating the complete shut down of the Napster file-swapping system, finding that it was appropriate to force Napster to entirely disable its service until copyright violations could be prevented with exacting precision.<sup>7</sup> In other words, the court was willing to provide broader protection than that provided under copyright law (stifling some uses of the Napster system that were perfectly legal) in order to preserve *at a minimum* the protection offered to copyright holders under that law.

In the context of patent law, the contours of a similar compromise have been drawn by statute. Section 271(c) of Title 35 of the U.S. Code provides that the marketing of a device capable of patented uses may be sold without fear of infringement liability, so long as the device has some “substantial noninfringing use.”<sup>8</sup> Additionally, § 271(b) imposes liability for sale of devices with substantial noninfringing uses (notwithstanding § 271(c)) in those cases where the seller knowingly encourages those who buy the device to use it in ways that will infringe method patents.<sup>9</sup> While these laws apply in all sorts of ways to all different kinds of patents, they do not apply, in certain circumstances, to pharmaceutical drugs. Herein lies the puzzle this paper presents.

The puzzle takes the form of a hypothetical. A pharmaceutical company develops a drug and patents both the drug and its use in treating disease X. The company obtains FDA approval for the drug, and rapidly develops both a healthy reputation in the medical community and a successful market. Through subsequent research, the company discovers that the drug is also effective in treating disease Y, and secures a third patent for its use to that end.

When the first two patents are about to expire, a competitor seeks FDA approval to manufacture and market a generic version of the drug. It is virtually certain, however, that if the generic version goes on the market, it will be prescribed by physicians, distributed by pharmacists, and ingested by patients, all for the purpose

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<sup>7</sup>A & M Records, Inc. v. Napster, Inc., 239 F.3d 1004 (9th Cir. 2001).

<sup>8</sup>35 U.S.C. § 271(c) (2003). The Sony court borrowed the “substantial noninfringing use” standard from this statute. *Sony*, 464 U.S. at 440.

<sup>9</sup>35 U.S.C. § 271(b) (2003).

of treating disease Y. Such use would, of course, be infringement of the third patent obtained by the first pharmaceutical company.

The question then arises: should the second generic manufacturer be precluded from creating the generic version of the drug in order to forestall infringement by unrelated third parties? On the one hand, it would be unfair to allow the second manufacturer to reap the benefits of the research and expense for which the first company was awarded its third patent. On the other hand, it would also be unfair to completely block competition in the drug after the expiration of the first two patents, since doing so would effectively extend the life of those patents beyond the term fixed under patent law.

Sections 271(b) and (c) have an answer to the question, of course. Production and sale of the drug is legal under § 271(b), since it is clearly capable of noninfringing uses. Sale of the drug is legal under § 271(c) as well, with the caveat that the generic manufacturer must not do anything to encourage its purchasers to use the drug to treat disease Y, or else the generic manufacturer will be liable for inducing infringement. Of course, drawing a line between “sale” and “sale plus encouragement” is a tricky question in its own right.<sup>10</sup> But in this particular situation, the problem is made manifestly more difficult due to the fact that in the context of FDA approval of drugs, patent rights are governed by what is known as the Hatch-Waxman Act — a complex scheme of laws designed to correct many of the special problems in patent that arise as a function of FDA regulation of (often patented) drugs.<sup>11</sup>

The intricacy of this scheme was highlighted recently in another pair of high-profile cases, this time before separate panels of the Federal Circuit. *Warner-Lambert v. Apotex*<sup>12</sup> and *Allergan v. Alcon*<sup>13</sup> both analyzed

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<sup>10</sup>5 DONALD S. CHISUM, CHISUM ON PATENTS § 17.04 (2003) (examining doctrine of inducement of infringement and reviewing cases).

<sup>11</sup>Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>12</sup>316 F.3d 1348 (Fed. Cir. 2003).

<sup>13</sup>2003 U.S. App. LEXIS 6003 (Fed. Cir. March 28, 2003) (per curiam).

a set of facts virtually identical to those presented in the hypothetical earlier, both applied Hatch-Waxman, and yet they came to diametrically opposing conclusions. The latter of the panels (*Allergan*) applied (as it was obliged to do) in a *per curiam* decision the precedent-setting reasoning of the first (*Warner-Lambert*).<sup>14</sup> Then, in a highly unusual move, all three members of the panel concurred in opinions criticizing the precedent, explaining in detail why they would have handed down the exact opposite decision were they not bound by the opinion of the *Warner-Lambert* panel.<sup>15</sup>

This paper is an attempt to resolve their debate in anticipation of the inevitable *en banc* review. Part I presents a review of the history of the Hatch-Waxman Act and its general operation in practice. Part II analyzes three issues of contention between the Federal Circuit panels, the third and foremost of which presents the ultimate question of whether Hatch-Waxman permits an action for infringement in the hypothetical detailed above. Part III concludes with a summary policy analysis of the outcome ultimately proposed.

## I.

### The Act: Hatch-Waxman

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (after the names of its principal sponsors), represented a compromise between pioneer and generic drug manufacturers who were both unsatisfied with what they saw as undesirable side effects of the combination of the extant laws governing drug approval and patents. Pioneer drug manufacturers (“pio-

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<sup>14</sup>*Id.* at \*5.

<sup>15</sup>*Id.* at \*36 (Schall, J., concurring); *id.* at \*68 (Linn, J., concurring). Judge Clevenger joined Judge Schall’s concurring opinion. *Id.* at \*1.

neers”) had been complaining that the prolonged regulatory review required by the 1962 amendments to the Food, Drug, and Cosmetics Act effectively and substantially diminished the length of the term of any patent associated with the drug.<sup>16</sup> Since patents on drugs were often already issued by the time regulatory review first began, “the ‘clock’ on [the] patent term [would] be running even though [the pioneer would] not yet [be] able to derive any profit from the invention.”<sup>17</sup>

At the same time, generic drug manufacturers (“generics”) had been griping about the effects of the premarket approval requirements at the other end of the patent term, especially in light of a 1984 case handed down by the Federal Circuit, *Roche v. Bolar*.<sup>18</sup> In *Roche*, a patentee had sued a generic drug manufacturer that had started producing small amounts of a drug covered by the patent that was going to expire within the next six months, in order to start performing the tests required to be able to submit a New Drug Application (NDA) to FDA, as was required before the company could market the drug. The generic company contended that while such “use” might fall under a literal reading of the patent infringement statute,<sup>19</sup> the court should find the activity excepted under the traditional “experimental use exception” created at common law.<sup>20</sup> Alternatively, the company argued that “public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing.”<sup>21</sup>

The court rejected these arguments and held the generic company liable for patent infringement. Incensed at the fact that “the combined effect of the patent law and the premarket regulatory approval requirement... create[d] an effective extension of the [pioneers’] patent term[s],”<sup>22</sup> the generics immediately demanded a legislative fix. They found a champion in Henry Waxman of the House of Representatives, who urged that

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<sup>16</sup>See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 580 (2d ed. 1991) (discussing the “drug lag.” resulting from the 1962 Drug Amendments).

<sup>17</sup>*Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990).

<sup>18</sup>733 F.2d 858 (1984).

<sup>19</sup>35 U.S.C. § 271(a) provides that “whoever without authority makes, uses, offers to sell, or sells any patented invention... during the term of the patent therefor, infringes the patent.”

<sup>20</sup>*Roche*, 733 F.2d at 862.

<sup>21</sup>*Id.*

<sup>22</sup>*Eli Lilly*, 496 U.S. at 670.

*Roche* be overruled through the addendum of a set of provisions to a patent term extension bill that had already cleared the Senate.<sup>23</sup> The compromise legislation was quickly engineered, and the result was the 1984 Hatch-Waxman Act.

Central to the practical import of the Act was the streamlining of the abbreviated NDA (ANDA) procedure through which generic counterparts to already-authorized pioneer drugs could obtain FDA approval, a procedure that has remained roughly the same for the nearly twenty years since the passage of the Act. Perhaps the most critical change is that now a generic drug manufacturer desiring to obtain FDA approval for a new generic version of an existing drug need not show safety and effectiveness of the generic version, but rather only its bioavailability and bioequivalence to the pioneer drug.<sup>24</sup> Moreover, the statutory language overruling *Roche* makes it clear that experimental tests on a patented drug performed to collect data required by the ANDA procedure (e.g., to show bioequivalence) will not constitute infringement of the patents associated with the drug.<sup>25</sup>

Yet while generic manufacturers enjoy this safe harbor for the purposes of drug testing, they are not permitted to avoid the patent confrontation indefinitely. With the actual filing of the ANDA to FDA, the generic company is generally required to submit a patent “certification” declaring the existence and application of certain patents associated with the relevant pioneer drug.<sup>26</sup> To assist the generic manufacturer in making this declaration, holders of NDAs for pioneer drugs are required to identify and register with FDA all known patents that claim those drugs or uses of those drugs for which NDAs were filed.<sup>27</sup> This list of patent information is, in turn, compiled by FDA and made publicly available in the so-called “Orange Book.”

The ANDA applicant is generally required to submit one certification for each of the patents associated with

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<sup>23</sup>Gerald J. Mossinghoff, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD DRUG L.J. 187 (1999).

<sup>24</sup>HUTT & MERRILL, *supra* note 16, at 571.

<sup>25</sup>35 U.S.C. § 271(e)(1).

<sup>26</sup>21 U.S.C. § 355(j)(2)(A)(vii).

<sup>27</sup>21 U.S.C. § 355(b)(1).



the pioneer drug corresponding to the proposed generic version for which approval is sought. For each such patent, the applicant must state one of the following: “(I) that the patent information has not been filed [e.g., it is not in the Orange Book], (II) that such patent has expired, (III)... the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”<sup>28</sup> In the first or second cases, the ANDA may be approved by FDA immediately; in the third, it may be approved on a date not before the patent expiration date given.<sup>29</sup>

The last sort of certification, often referred to as a “Paragraph IV certification,” may generate a much more complex sequence of events, as detailed in the statute. First, an ANDA applicant submitting a Paragraph IV certification is required to give notice of the certification to both the patent holder as well as the holder of the NDA for the corresponding pioneer drug, including “a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.”<sup>30</sup> If the parties notified do not do take any further action for forty-five days after receipt of the notice, the ANDA may be approved immediately.<sup>31</sup> If, however, a claim for patent infringement is brought against the ANDA applicant within the forty-five day window, then FDA approval will automatically be withheld for thirty months, barring a decision before that time by the court where suit is brought that the patent is or is not infringed.<sup>32</sup>

To ensure that just such a judicial determination is possible, the Act explicitly states that it “shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug... before the expiration of such patent.”<sup>33</sup> Of course, on its face, such

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<sup>28</sup>21 U.S.C. § 355(j)(2)(A)(vii). With respect to Paragraph I, see *Allergan*, 2003 U.S. App. LEXIS 6003, at 61 n.12.

<sup>29</sup>21 U.S.C. § 355(j)(5)(B).

<sup>30</sup>21 U.S.C. § 355(j)(2)(B).

<sup>31</sup>21 U.S.C. § 355(j)(5)(B)(iii).

<sup>32</sup>*Id.*

<sup>33</sup>35 U.S.C. § 271(e)(2).

a definition of infringement would seem to encompass, at the very least, *any* act of filing an ANDA with a Paragraph IV certification, since the very nature of the certification indicates that the applicant intends to “engage in the commercial manufacture, use, or sale of a drug... before the expiration of [the corresponding] patent.”<sup>34</sup>

The courts have declined to thus interpret the infringement provision as a “strict liability statute,”<sup>35</sup> saving the provision from this absurd result by reading it as prohibiting only the submission of an ANDA “*that is in error* as to whether commercial manufacture, use, or sale... [will] violate[] the relevant patent.”<sup>36</sup> The Federal Circuit has held that a court’s inquiry in a suit brought under § 271(e)(2) is, in essence, “the same as it is in any other infringement suit, viz., whether the patent in question is ‘invalid or will not be infringed by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.’”<sup>37</sup>

While such an inquiry is in a sense “highly artificial,”<sup>38</sup> since its focus is on a product that “has not yet been made, used, or sold,”<sup>39</sup> in fact, the whole point of the infringement action is to create “a jurisdictional construct to enable patentees to get into court quickly before a potentially infringing product gets out into the market.”<sup>40</sup> Such a goal is, of course, part of the general compromise of the Act that aims to allow generic companies to roll out products quickly when pioneer drug patent terms expire, while still providing assurance to patentees that rights in those patents that remain extant will be protected.

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<sup>34</sup>*Id.* See *Organon Inc. v. Teva Pharms., Inc.*, 244 F. Supp. 2d 370, 378 (D.N.J. 2002) (noting that the “literal wording of § 271(e)(2) of the Hatch-Waxman Act... states that it shall be an act of infringement to file an ANDA with a paragraph IV certification”); *Allergan, Inc. v. Alcon Labs.*, 200 F. Supp. 2d 1219, 1227 (C.D. Cal. 2002) (stating that the “literal reading of the statute is naturally problematic, as it would. . . appear to exclude traditional defenses such as invalidity and non-infringing use”).

<sup>35</sup>*Allergan*, 2003 U.S. App. LEXIS 6003, at \*35 n.6; *Warner-Lambert*, 316 F.3d at 1355 (rejecting the argument that “the mere filing of an ANDA for a drug having a use claimed in a patent is an infringing act per se”).

<sup>36</sup>*Eli Lilly*, 496 U.S. at 678.

<sup>37</sup>*Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

<sup>38</sup>*Eli Lilly*, 496 U.S. at 678.

<sup>39</sup>*Glaxo*, 110 F.3d at 1569.

<sup>40</sup>*Organon*, 244 F. Supp. 2d at 378.

## II.

### The Debate: A Circuit, Split

The Hatch-Waxman Act is a truly ambitious piece of legislation, and in many respects has fulfilled well its purposes. But it has been a bumpy ride. Courts and commentators often quote the critique that appears in *Eli Lilly*: “No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.”<sup>41</sup> The general feeling is that the critique is not only well earned, but is appropriately applied to the Act as a whole. One example of the drafting imprecision has just been discussed: the plain but difficult language of the new patent infringement provision.<sup>42</sup> But while that interpretive move was made without much notice or controversy, not all of the puzzles of Hatch-Waxman have fared so well. This is nowhere better seen than in the sharply contrasting decisions in *Warner-Lambert* and *Allergan*. This Part takes up three particularly knotty issues raised in those two cases, and tries to draw some conclusions about the correct answer to the problem posed in the beginning, in light of the most reasonable interpretation of the Hatch-Waxman Act.

## A.

### The Listing Provisions

Pioneer drug manufacturers are required, as part of the NDA process, to submit patent information to FDA according to § 355(b)(1):

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<sup>41</sup> *Eli Lilly*, 496 U.S. at 679.

<sup>42</sup> 35 U.S.C. § 271(e)(2).

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

The statute goes on to explicitly state, in § 355(c)(2), that patents obtained post-NDA-approval should also be filed with FDA. Do § 355(b) and (c) require the filing of those patents associated with uses of a drug that are not covered by an NDA? The question is a critical one, since other portions of the statute (the patent certification provision, for one) attach certain consequences depending on whether such patents are “required to be filed under subsection (b) and (c).”<sup>43</sup>

*Warner-Lambert* suggests that the answer is no. For support, the court places emphasis on the last part of the provision, “with respect to which a claim of patent infringement could reasonably be asserted,” taking this to mean only “relevant patents” may be filed.<sup>44</sup> The *Warner-Lambert* panel also relies heavily on 21 C.F.R. § 314.53, an FDA regulation that clearly mandates that only use patents that claim a use approved under an NDA may be filed for inclusion in the Orange Book.<sup>45</sup> Indeed, FDA has made it clear that they agree with the more restrictive reading of § 355(b) that *Warner-Lambert* adopts here.<sup>46</sup>

Judge Schall, however, takes the opposite position in his *Allergan* concurrence, (joined by Judge Clevenger).

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<sup>43</sup>21 U.S.C. § 355(j)(2)(A)(vii).

<sup>44</sup>*Warner-Lambert*, 316 F.3d at 1361.

<sup>45</sup>*Id.* at 1361 n.6 (“For patents that claim a method of use, the FDA regulations state that ‘the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.’”) (citing 21 C.F.R. § 314.53(b)). The district court in *Allergan* took the same position. *See Allergan*, 200 F. Supp. 2d at 1230 n.9.

<sup>46</sup>Proposed Rule, Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed, 67 Fed. Reg. 65448, 65452 (October 24, 2002) (noting that under both the existing rule and its proposed amendment, “patents that claim methods of use that are not approved for the listed drug or are not the subject of a pending application may not be submitted [for inclusion in the Orange Book]”). For this reason it is perhaps curious that the *Allergan* defendants attempted to argue that the proposed rule amendment provided additional support for their narrow interpretation of § 355(b), since the amendment would not seem to either add or take away support for their position. *See Allergan*, 2003 U.S. App. LEXIS 6003, at \*54 n.10.

Judge Schall first notes that the plain statutory language states that “*any* patent... which claims a method of using [the] drug” should be filed,<sup>47</sup> and that there is no explicit limitation that the method of using the drug be the one approved in the original NDA.<sup>48</sup> With regard to the FDA rule, he notes that it should be construed, if at all possible, so as to be consistent with (his reading of) the statute: “A court is properly reluctant to embrace a reading of a regulation that makes the regulation conflict with the statute that it is meant to implement.”<sup>49</sup> He ultimately finds it capable of such a construction. Furthermore, Judge Schall expresses reluctance to rely on the proceedings of a proposed rulemaking that would make it even clearer that the FDA rule bars submission of non-controlling use patents.<sup>50</sup>

Surely Judge Schall is correct that an agency’s interpretation cannot override the clear language of a statute; under *Chevron*, a reviewing “court, as well as [an] agency, must give effect to the unambiguously expressed intent of Congress.”<sup>51</sup> The question is whether § 355(b) can indeed be considered unambiguous. Judge Schall’s explication suggests that it is. By contrast, *Warner-Lambert*’s reliance on the phrase “with respect to which a claim of patent infringement could reasonably be asserted” smacks of circularity, for the issue of whether or not all related use patents should be submitted to FDA (including those disclosing uses not approved in the original NDA) bears on the very question of whether a patentee will be *able* to sue for infringement. To state that NDA applicants are required to list only “relevant patents” is to beg the question of “relevance.” In contrast, Judge Schall’s interpretation is clearly grounded in the text of the statute.

Section 355(b) must therefore be interpreted as requiring submission of all valid patents claiming methods

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<sup>47</sup>*Allergan*, 2003 U.S. App. LEXIS 6003, at \*48 (Schall, J., concurring) (emphasis added in opinion).

<sup>48</sup>*Id.* at \*50 (Schall, J., concurring).

<sup>49</sup>*Id.* at \*53 (Schall, J., concurring). Judge Schall cites *Whitman v. Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 484 (2001) and *Gomez v. Dept. of Air Force*, 869 F.2d 852, 858 (5th Cir. 1989) to support his argument here. *Id.* at \*52-\*53 (Schall, J., concurring).

<sup>50</sup>*Id.* at \*54 (Schall, J., concurring), quoting *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 845 (“It goes without saying that a proposed regulation does not represent an agency’s considered interpretation of its statute and that an agency is entitled to consider alternative interpretation before settling on the view it considers most sound.”).

<sup>51</sup>*Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843 (1984). *See also* *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-126 (2000) (finding that FDA did not have statutory authority to regulate tobacco products, notwithstanding their attempts through rulemaking to do so).

of using a drug that is the subject of an associated NDA.<sup>52</sup>

## B.

### The Certification Provision

The provision governing patent certification, on the other hand, is much less straightforward. The text of § 355(j)(2)(A)(vii) runs thus:

[An ANDA shall contain] a certification... with respect to each patent which claims the listed drug... or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section....

The principal ambiguity of the language has to do with the phrase “for which the applicant is seeking approval.” Does the statute require certification for patents that claim *uses* (of a drug) for which the applicant is seeking approval? Or does it require certification for patents that claim uses of a *drug* for which the applicant is seeking approval?

The immediate context of the provision suggests one mode of clarification. The following paragraph, § 355(j)(2)(A)(viii) states that

if information was filed under subsection (b) or (c) of this section for *a method of use patent which does not claim a use for which the applicant is seeking approval* under this subsection, [then the ANDA applicant must submit] a statement [to that effect].

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<sup>52</sup>One court has noted that notwithstanding the FDA rule, “it is common for pioneers to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file paragraph IV certifications.” *Organon v. Mylan*, 2002 U.S. Dist. LEXIS 24219, at \*12 n.6 (D.N.J. December 18, 2002). The court adds that “FDA does not appear to have policed this practice.” *Id.* On the other hand, it is also clear that “[l]isting in the ‘Orange Book’ is entitled to no presumption about the validity of the drug or patent owner’s claims, and is a ministerial act on the part of the FDA.” *Allergan*, 200 F. Supp. 2d at 1223.

A reading of these two provisions in succession suggests that they are intended to be complementary, especially given the parallel inverse phrases “for which the applicant is/is not seeking approval.” In other words, since it is clear that the second paragraph (viii) refers to the case of a patent claiming a method of use for which the ANDA applicant is *not* seeking approval, then it would seem reasonable to assume that the first paragraph (vii) is meant to exclude that case.<sup>53</sup> The *Warner-Lambert* panel appears to adopt this interpretation, implying that the two paragraphs are indeed meant to be mutually exclusive.<sup>54</sup> Other courts have adopted this stance even more explicitly,<sup>55</sup> as has FDA: “The two provisions of the statute [paragraphs (vii) and (viii)] do not overlap.”<sup>56</sup>

A closer look at the language of the statute, however, reveals several complexities that must be addressed before arriving at a definitive conclusion. First, it seems peculiar that paragraphs (vii) and (viii) would be connected with the conjunctive “and” rather than the disjunctive “or” if they were truly intended to be mutually exclusive.<sup>57</sup> Would it not have made more sense for Congress to have combined the two possibilities into a single statutory element if the *Warner-Lambert* interpretation were correct? On the other hand, the mere fact that Congress might have drafted the provision more clearly is not exactly convincing affirmative evidence of an alternative reading; after all, if Congress intended the opposite interpretation, it could just as easily be argued that they should have made the language clearer to that end.

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<sup>53</sup>The plaintiff in *Warner-Lambert* tried to turn this analysis on its head by arguing that the interposition in section (vii) of the words “for such listed drugs” within the phrase “use for which the applicant is seeking approval” indicates that the similar phrases in sections (vii) and (viii) cannot be considered complementary. *Warner-Lambert*, 316 F.3d at 1362. The court rightly rejected the argument as “unconvincing.” *Id.* Clearly the interposition of “for such listed drugs” results from the fact that section (vii) applies to patents on both drugs and uses. Since section (viii) deals only with uses, there would be no reason for it to also interpose the phrase “for such listed drugs.”

<sup>54</sup>*Warner-Lambert*, 316 F.3d at 1362 (noting that for a drug with multiple approved indications, an ANDA applicant might have to certify some patents under subsection (vii) and others under subsection (viii)).

<sup>55</sup>*See, e.g.,* *Purepac v. Thompson*, 2002 U.S. Dist. LEXIS 24219, at \*11 (D.D.C. December 16, 2002) (noting that under certain circumstance, the “ANDA applicant need not file a patent certification under [section (vii)]; instead, the ANDA must include a statement [under (viii)] that the method of use patent at issue does not claim the use of the drug for which the applicant is seeking approval”).

<sup>56</sup>Letter from Gary Buehler of FDA to Apotex and Purepac, January 28, 2003, at <http://www.fda.gov/cder/ogd/75350.479pat.pdf>.

<sup>57</sup>*See* 21 U.S.C. § 355(j)(2)(A) (stating that an ANDA shall contain a certification under (vii), if applicable, “and” a statement under (viii), if applicable). *But see Warner-Lambert*, 316 F.3d at 1362 (rejecting this argument).

Second, the *Allergan* concurrence claims additional textual support for an opposing interpretation in the parallel phrases “for which” in paragraph (vii).<sup>58</sup> The implications of such a reading is made clear by aligning the clauses like so:

[An ANDA shall contain] a certification... with respect to each patent...  
which claims a use for such listed drug

[1] for which the applicant is seeking approval under this subsection and

[2] for which information is required to be filed under subsection (b)....

The second clause must be understood as applying to the word “drug,” Judge Schall contends, because § 355(b) sets forth the list of data regarding the *drug* for which the NDA applicant is applying.<sup>59</sup> If the second clause is anchored to “drug,” then it should be expected that the first clause would also be so anchored, so as to be consistent with the “parallel construction of the sentence.”<sup>60</sup> However, while it certainly seems true that the two clauses must attach to the same word, it would appear that, in fact, the second clause could just as plausibly be read as connecting to “use” rather than to “drug,” since one of the things § 355(b) requires to be submitted is a list of patents governing *uses* of a drug, as discussed in Section A, above.

Third, Judge Schall asserts that the *Warner-Lambert* interpretation of § 355(j)(2)(A)(vii) would lead to a “distorted interpretation” of § 355(b): why would NDA applicants be required to file *all* use patents with FDA if only some of them generated certification requirements under section (vii)?<sup>61</sup> The likely response is that while some such patents would be listed in the Orange Book to put generic companies on notice for the purposes of the section (vii) certification, the others could be understood as putting the same companies on notice for the purposes of the section (viii) statement.

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<sup>58</sup> *Allergan*, 2003 U.S. App. LEXIS 6003, at \*56-\*58 (Schall, J., concurring).

<sup>59</sup> *Id.* at \*57 (Schall, J., concurring).

<sup>60</sup> *Id.* (Schall, J., concurring).

<sup>61</sup> *Id.* at \*61-\*62 (Schall, J., concurring).



A final argument in opposition to the mutual exclusivity interpretation has to do with the implications of that interpretation within the larger context of the Act. An examination of the surrounding statutory provisions reveals that the filing of the certification under § 355(j)(2)(A)(vii) is central to the entire complex operation of the ANDA proceeding. Proceedings involving Paragraph VI certifications, of course, are subject to special procedures under this scheme, such as the requirement of notice to be sent to patentees and NDA holders<sup>62</sup> and the 180-day period of marketing exclusivity for first-time filers.<sup>63</sup> But all four types of certification are subject to a separate provision regulating timing of ANDA approval, depending on the type of certification submitted (as detailed in Part I).<sup>64</sup> That provision could be read as evidence that Congress imagined that *all* ANDA applicants would submit some sort of certification under section (vii) — even if only to state that there were no existing patents or no patents that applied to that particular ANDA (i.e., a Paragraph I certification).<sup>65</sup> But such a reading would ultimately require only a minor adjustment to the *Warner-Lambert* interpretation of section (vii), the implication being that while the two provisions are not mutually exclusive, a section (viii) statement should always be accompanied by a Paragraph I certification, essentially stating that section (vii) does not apply to the particular ANDA under consideration. This would avoid any unnecessary ambiguities regarding timing of approval that might accrue were section (viii) statements understood as precluding the need to file a certification under section (vii).

The combined effect of these counterarguments make the interpretive decision a close call, but at the end of the day, there appears to be no ready argument to overcome the *Warner-Lambert* interpretation based on the complementarity of the language of sections (vii) and (viii). It would appear that with respect to patents claiming uses for which an ANDA applicant is not seeking approval, the statute requires only a section (viii) statement, possibly in connection with a Paragraph I certification, but probably not a Paragraph IV

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<sup>62</sup>21 U.S.C. § 355(j)(2)(B).

<sup>63</sup>21 U.S.C. § 355(j)(5)(B)(iv).

<sup>64</sup>21 U.S.C. § 355(j)(5)(B)(i)-(iii).

<sup>65</sup>21 U.S.C. § 355(j)(2)(A)(vii)(I) (certification stating that “that such patent information [that is, the sort of patent information whose existence is postulated in the preamble to 21 U.S.C. § 355(j)(2)(A)(vii)] not been filed”).

certification under section (vii).

## C.

### The Infringement Provision

#### 1.

##### Paragraph IV Problems

Having dealt with these preliminaries, the big question can finally be tackled: is a claim of induced infringement cognizable under 35 U.S.C. § 271(e)(2) when the drug use claimed in the patent at issue has not been approved by the FDA? The statutory language of § 271(e)(2) reads:

It shall be an act of infringement to submit... an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The first point to notice about the infringement provision is that it makes *absolutely no mention of a Paragraph IV certification*. This is a detail that appears to have inexplicably escaped the attention of most of the courts that have analyzed the provision.<sup>66</sup> For example, the district court in *Allergan* unabashedly opines that “[i]t is the filing of a Paragraph IV Certification that puts into process the notice to the patentee

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<sup>66</sup> See, e.g., *Astra Aktiebolag v. Kremers Urban Development*, 222 F. Supp. 2d 423, 439 (S.D.N.Y. 2002) (“Section 271(e)(2)(A) provides a patentee with a cause of action for patent infringement based solely upon the filing of an ANDA containing a Paragraph IV certification implicating a plaintiff’s patent rights.”); *Purepac*, 2002 U.S. Dist. LEXIS 24219, at \*11-\*12 (“An applicant proceeding by means of a section viii statement... does not face an infringement action under 35 U.S.C. § 271(e)(2)(A)”).

allowing it to bring suit under Section 271(e)(2).<sup>67</sup> Indeed, even the Supreme Court, in its construal of the statute in *Eli Lilly*, implies that the submission of a Paragraph IV certification is an essential element of the § 271(e)(2) infringement action.<sup>68</sup>

Of course, this is not to say that submission of a Paragraph IV certification has no effect on possible infringement proceedings. On the contrary, as was detailed in Part I, when an infringement proceeding is brought within 45 days of receipt of notice of a Paragraph IV certification, that suit immediately triggers a 30-month stay on approval of the underlying ANDA, unless the patent issue is found to be invalid before that period has expired.<sup>69</sup> The patentee who sues a generic drug manufacturer who has submitted no such certification cannot enjoy the obvious benefits of the 30-month stay, and thus the generic drug of disputed legitimacy may be FDA-approved and marketed even while the patent dispute is still pending (assuming, of course, that such a suit can be brought in the first place).<sup>70</sup>

Moreover, it is not surprising that a Paragraph IV certification would get read into § 271(e)(2) considering how such certification inherently presupposes an applicant's contemplation of commercial activity before the expiration of a patent (even while asserting that the patent is invalid or otherwise will not be infringed by such activity). Contrast the nature of certifications under Paragraphs I through III, none of which appears on its face to disclose an intent (as required under § 271(e)(2)) "to engage in the commercial manufacture, use, or sale of a drug... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." For example, any company that decided to delay production of a generic drug until after the expiration of an existing patent would presumably file under Paragraph III in the first place. There is no reason to think that such a company would be liable for infringement under § 271(e)(2). Up to this point,

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<sup>67</sup> *Allergan*, F. Supp. 2d at 1230.

<sup>68</sup> *Eli Lilly*, 496 U.S. at 678 ("That is what is achieved by § 271(e)(2) — the creation of a highly artificial act of infringement that consists of submitting an ANDA... *containing the fourth type of certification* that is in error as to whether commercial manufacture, use, or sale of the new drug... violates the relevant patent.") (emphasis added).

<sup>69</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>70</sup> See *Purepac*, 2002 U.S. Dist. LEXIS 24219, at \*11-\*12 (noting that ANDAs submitted under section (viii) are not subject to the notice requirements or the 30-month stay). Of course, these applicants cannot reap the benefits of a possible 180-day period of exclusivity, either. *Id.* at \*12.

then, there would appear to be no problem with the Paragraph IV incorporation interpretation.

In fact, the trouble with the interpretation becomes apparent only in a scenario precisely like the one under general consideration in this paper. A generic company planning to sell an unpatented drug with certain patented uses does not have to submit a Paragraph IV certification to FDA (as was argued in Section B, above) but nonetheless certainly plans “to engage in the commercial manufacture... of a drug... the use of which is claimed in a patent before the expiration of such patent,” as presumptively prohibited by § 271(e)(2). If a Paragraph IV certification is a requirement for suit under § 271(e)(2), this patentee is out of luck. But what reason can there be to read such a requirement into the statute to begin with? No court even attempts to offer any explanation.

Nor can the *Eli Lilly* restatement of § 271(e)(2) (which presumably started the Paragraph IV incorporation trend) be cured by simply excising the reference to Paragraph IV. Such a reformulation of the *Eli Lilly* rule would prohibit the submission of an ANDA “that is in error as to whether commercial manufacture, use, or sale... [will] violate[] the relevant patent.”<sup>71</sup> But where is the error in the ANDA in the hypothetical case above, where the application is for an unpatented drug with some patented uses? When the ANDA applicant states under section (viii) that the patent in question covers a use for which approval is not being sought, such a statement is entirely *true*. However, whether or not the statement is true has no bearing on whether the applicant’s activities might be considered inducement of infringement. Why deny the patentee’s claim when the statute says nothing about requiring an “error”?

Fortunately, the Federal Circuit ultimately gets things right in *Glaxo* when it ignores the Supreme Court’s gloss on § 271(e)(2) and asserts that the inquiry under Hatch-Waxman is “the same as it is in any other

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<sup>71</sup> *Eli Lilly*, 496 U.S. at 678.

infringement suit”: whether the patent is valid and (if so) whether the product that the ANDA applicant is likely to market will infringe that patent. The interpretation succeeds (unsurprisingly) by not looking for anything in § 271(e)(2) that was not there to begin with.<sup>72</sup>

## 2.

### Antecedence Nonsense

Under *Glaxo*, it would thus appear that the hypothetical patentee can at least get into court to have its inducement of infringement claim heard. In the *Warner-Lambert* opinion, however, the Federal Circuit panel puts one final spin on § 271(e)(2) that needs first to be addressed. Recall once more that § 271(e)(2) prohibits (under certain conditions) the submission of an ANDA for a drug “the use of which is claimed in a patent.” *Warner-Lambert* interprets the phrase “the use” here to mean “the use for which the FDA has granted an NDA.”<sup>73</sup> Hence, under *Warner-Lambert*, a § 271(e)(2) infringement suit may be maintained with respect to a drug use patent only where that drug use has been approved by the FDA.<sup>74</sup>

The *Warner-Lambert* panel explains that Congress’s choice of the word “the” before “use” is highly significant: “The words ‘the use’ require antecedent basis; thus ‘the use’ refers to a specific ‘use’ rather than a previously undefined ‘use.’”<sup>75</sup> The panel finds an antecedent basis in 21 U.S.C. § 355(j)(2)(A)(i), a provision requiring the ANDA applicant to “show that the conditions of use prescribed, recommended, or suggested

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<sup>72</sup>For example, when § 271(e)(2) talks of “a drug... the use of which is claimed in a patent,” it implicitly requires as the elements of liability a legitimate patent (validity) and a use that falls within the claims of that patent (infringement).

<sup>73</sup>*Warner-Lambert*, 316 F.3d at 1356.

<sup>74</sup>*Id.* (“[B]ecause an ANDA may not seek approval for an approved or off-label use of a drug... it necessarily follows that 35 U.S.C. § 271(e)(2)(A) does not apply to a use patent claiming only such a use.”).

<sup>75</sup>*Id.*

in the labeling proposed for the new drug have been previously approved [under a prior NDA].”<sup>76</sup> Such an antecedent makes sense, the opinion explains, since when the FDA approves an ANDA, it only does so for the specific use or uses permitted under the original NDA.<sup>77</sup> The *Warner-Lambert* panel finally notes that if Congress had intended a contrary meaning, they surely would have used “a” or “any” instead of “the” in drafting the provision: “Congress could have been expected to use quite different language if it wanted to reach the opposite result.”<sup>78</sup>

All three members of the *Allergan* panel roundly criticize *Warner-Lambert* on this point, and with good reason; indeed, determining the proper meaning of “the use” is perhaps the easiest interpretive issue touched upon thus far in the paper.<sup>79</sup> Judge Linn reasons that “[t]here is no indication that Congress deliberately selected the definite article,” arguing that the “normal reading of ‘the use’ in this context is simply ‘any use.’”<sup>80</sup> Indeed, the idea that Congress intended to use the word “the” to make a reference to another provision in such a far-removed location is patent nonsense (so to speak).<sup>81</sup> Finally, the “Congress could have said” argument, rejected when advanced against the *Warner-Lambert* plaintiff in Section B, must be rejected here as well. The emptiness of the debate tactic is made evident when Judge Schall ultimately turns it against the *Warner-Lambert* panel, noting that Congress could have used the term “controlling use” instead of “the use” if it had wanted to make clear an intent to communicate the substance of the *Warner-Lambert* interpretation.<sup>82</sup>

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Allergan*, 2003 U.S. App. LEXIS 6003, at \*38 (Schall, J., concurring); *Id.* at \*70-\*72 (Linn, J., concurring).

<sup>80</sup> *Id.* at \*70 (Linn, J., concurring).

<sup>81</sup> While *Warner-Lambert* urges that “the use” be read “in the context of the Act,” *Warner-Lambert*, 316 F.3d at 1356, an examination of a print copy of the Hatch-Waxman Act finds “the use” and its purported antecedent basis at opposite ends of that Act. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1603 (1984) (showing the references on pages 1585 and 1603, respectively — eighteen pages apart in a twenty-page act).

<sup>82</sup> *Allergan*, 2003 U.S. App. LEXIS 6003, at \*39 (Schall, J., concurring).

### III.

#### The Conclusion: Compromise

Judge Linn’s most direct criticism for the *Warner-Lambert* panel comes when he accuses them of having “ventured beyond our interpretive role and, in interpreting the complex statutory scheme... [allowing] policy choices... to override the terms of the statute chosen by Congress.”<sup>83</sup> Whether Judge Linn’s criticism is rightly placed or not, the policy inquiry is one that courts routinely engage in when considering Hatch-Waxman, and when they do, more often than not, the consciously chosen policy goal is, like that of Hatch-Waxman itself, one of “compromise.”<sup>84</sup>

By the lights of compromise, the conclusions reached in this paper (though not determined by way of policy analysis) come out looking pretty good. Pioneer manufacturers are allowed to list all patents applicable to their drugs in the Orange Book to facilitate notice to the generics of those patents. The generics, in turn, are not obliged to submit Paragraph IV certifications for those patents that disclose uses not approved by the original NDA, thus escaping the notice requirements of Hatch-Waxman. To the extent that generic companies overstep their bounds and begin subtly promoting still-patented uses to potential customers, they can be held to answer in court for induced infringement. They will not, however, be automatically subject to 30-month stays; injunctive relief barring sale of the generic drug will be available at the discretion of the judge, and only through the traditional showing of irreparable harm, and so forth.

Consider, however, one final bit of political advice that might be added to this analysis, offered up from

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<sup>83</sup>*Id.* at \*69 (Linn, J., concurring).

<sup>84</sup>*Warner-Lambert*, 316 F.3d at 1358-59 (citing the Hatch-Waxman Act “compromise” and explaining how the plaintiff’s interpretations of the Act would upset that compromise).

the direction from whence this paper started: copyright law. From the advent of the VCR down into the Napster era, the trade associations representing the big copyright interests (e.g., the Recording Industry Artists of America, the Motion Picture Association of America) have been doing battle with the owners and distributors of technologies that are capable of and hence facilitate copyright violation. The lawsuits have been legion,<sup>85</sup> and they are fiercely fought by those who feel a certain injustice in the deprivation of a tool that is, in fact, capable of legal, and legitimate uses. “Don’t go after us!” the opponents to the copyright interests cry. “Go after the people who are actually stealing your stuff!” But the cries are usually dismissed, because the practical costs and difficulties in going after individual offenders are perceived to be tremendous when compared to the tactic of targeting middlemen instead.

In a matter of mere months, however, there has been a dramatic sea change. On April 3, 2003, the RIAA served complaints on four college students found to have illegally downloaded and distributed thousands of copyrighted works.<sup>86</sup> The penalties requested were moderately high — some \$98 billion in total damages<sup>87</sup> — and, of course, many commentators complained that the RIAA should not be asking for such ridiculous amounts, that they should not be picking on poor college students, *etcetera*.

On another level, of course, there seemed to be strangely little to complain about. These students had clearly violated copyright law (no strained analysis in the realm of inducing or vicarious infringement required), and, while they might not have thought they would get caught, they did, and the law is fairly clear regarding penalties. Catching the students could not have required a terribly large amount of resources. Since the law is clear, the litigation expenses will not be significant (indeed, it seems exceedingly doubtful the cases will

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<sup>85</sup>See, e.g., *Corley*, 273 F.3d at 429 (DVDs); *Sony*, 464 U.S. at 417 (VCRs); *Napster*, 239 F.3d at 1004 (file-sharing software); *RealNetworks, Inc. v. Streambox, Inc.*, 2000 U.S. Dist. LEXIS 1889 (W.D. Wash. January 18, 2000) (music software); *Sony Computer Entertainment Am., Inc. v. GameMasters*, 87 F. Supp. 2d 976 (N.D. Cal. 1999) (video games); *MGM Studios, Inc. v. Grokster, Ltd.*, 2003 U.S. Dist. LEXIS 6994 (April 25, 2003) (file-sharing software).

<sup>86</sup>See FindLaw News Document Archive, at <http://news.findlaw.com/legalnews/documents/index.html> (archiving copies of the complaints against the four students)

<sup>87</sup>Andrew Tibbetts, RIAA sues two RPI students, PolyTechnic Online (April 30, 2003) at [http://poly.union.rpi.edu/article\\_view.php3?view=2211&part=1](http://poly.union.rpi.edu/article_view.php3?view=2211&part=1). Of course, that is an amount generated for scare value; the suits will likely settle for a minute fraction of that figure.



ever go to trial). The file-trading tools are left available for those who want to use them, but it sent a strong warning out to possible future offenders. In short, it seems like it may just have been the most effective action taken by the copyright interests since the invention of the VCR.

Is there a lesson to be learned here for the pharmaceutical companies? In the middle of one unremarkable pioneer/generic lawsuit like the others here considered, Judge Hochberg of the U.S. District Court of New Jersey drops a helpful footnote.<sup>88</sup> Noting first that the defendants have “no control over doctors to absolutely prevent them from writing an infringing prescription,” she goes on to point out that, “Indeed,... it is Plaintiffs who have a large corps of drug salespersons who visit doctors regularly and can most readily police their own patent.”<sup>89</sup> Imagine, then, this scenario: four doctors are sued for having illegally prescribed a generic drug for treating disease Y (a patented method of use for the drug). The law is clear. The expense is low. The deterrence is high. And those who want to have access to a cheap generic drug for treating disease X will still be able to get it.

Might not such an approach strike the best balance of all — maximizing the benefits of use, and minimizing the harms of abuse? It sounds like it might be a pretty good compromise.

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<sup>88</sup> *Organon*, 244 F. Supp. 2d 370, n.13.

<sup>89</sup> *Id.*